AUG 1 3 2001

K011906

Summary of Safety and Effectiveness

General Provisions	**Trade Name**: Back-Up Meier Guidewire **Classification Name:** Wire, Guide
Name of Predicate Devices	Platinum Plus Guidewire Amplatz Super Stiff Guidewire
Classification	Class II
Performance Standards	Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act
Intended Use and Device Description	The Back-Up Meier Guidewires are intended to facilitates placement of a catheter during diagnostic or interventional intravascular procedures The Back-Up Meier Guidewires are sterile, single-use wires and are available in different tip shapes with overall wire lengths of 185 cm – 300 cm. The distal segment of the wire is radiopaque to aid in visualization of the device under fluoroscopy.
Biocompatibility	The Back-Up Meier Guidewires have been tested for biocompatibility per ISO 10993. All data demonstrate this device is biocompatible for its intended use.
Summary of Substantial Equivalence	The Back-Up Meier Guidewires have been tested and compared to the predicate devices. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 3 2001

Ms. Jodi Lynn Greenizen
Regulatory Affairs Project Manager
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Re: K011906
Back-Up Meier Steerable Guidewire
Regulation Number: 870.1330
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: June 18, 2001
Received: June 19, 2001

Dear Ms. Greenizen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known)	Unknown K011906
Device Name:	Back-Up Meier Guidewire
Indications for Use	The Back-Up Meier Guidewire is intended to facilitate placement of a catheter during diagnostic or interventional intravascular procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011906

Prescription Use ✓ OR Over-The Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)